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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,289	07/11/2001	Peter A. Burke	3056	8411

7590

07/30/2003

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/903,289

Applicant(s)

BURKE ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 and 12 is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Amendment filed April 15, 2003 has been received, entered into the record and carefully considered. The following information provided in the amendment affects the instant application:

1. Remarks drawn to rejections under 35 USC 103.

Claims 1-12 are pending.

#### ***Claim Objections***

Claims 6 and 9 are objected to because of the following informalities: The term "claims" in claim 6 and the term "activiral" in claim 9 should be changed to "claim" and "antiviral" respectively. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-8 recite the package of claim 1 including acrylic acid polymer, lubricants, detergent and cellulosic binder respectively. It is not clear if these are separately in the package or they are present in the composition. Also, in claim 8 it is not clear if the composition or the non-mucosal area includes the cellulosic binder. The claim

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is ambiguous. The recitation "for use in a non-mucosal area" is intended use and does not constitute a patentable limitation.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopes (USPN 5,942,478) in combination with Larsen (USPN 5,958,461), Stoner (USPN 4,925,033), Myhling (USPN 5,527,534), Snyder et al (USPN 5,674,513) of record Taylor-McCord (USPN 5,604,200) of record in the previous office action is withdrawn is withdrawn. The following new rejection is made of record.

Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsen (USPN 5,958,461) in combination with Ueno et al (US 4869270) and Stoner (US 4925033).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9 and 10 are drawn to a package containing a condom and an antiviral composition in the form of a gel which comprises an effective amount of microbicidal agent, a buffer to maintain the pH of the composition not greater than 5, an effective amount of wound healing and diffusion impedance compound, the composition containing a spermicidal, an acrylic acid polymer and lubricants.

Larsen teaches a gelled vaginal contraceptive composition which comprises an acrylic acid modified polymer, an active spermicidal agent and a buffer to maintain the pH of the composition between 3 and 6. The spermicidal agent in Larsen's composition is nonoxynol-9 (see col. 10, lines 13-28; col. 8, examples 2-4). Larsen mentions dextran sulfate as one of the ingredients which can be used in the composition as an antiviral agent but not as a wound healing and diffusion impedance compound.

Ueno et al teach the use of an aqueous solution of a polysaccharide selected from the group consisting of dextran sulfate, hyaluronic acid and their pharmaceutically acceptable salts with lubricants for applying to the surface of a condom (see col. 1, line 55 through col. 2, line 5 and examples in col. 3). Ueno et al also disclose that other water soluble materials like glycerin, glycols and polyglycols as wetting materials (see col. 2, lines 55-60) which one of ordinary skill in the art will realize also can act as lubricants. According to Ueno et al the polysaccharides used in their composition also serve as lubricants (see col. 1, lines 43-50). Further, dextran sulfate, hyaluronic acid and their salts have a protecting effect on a wounded site (see col. 2, lines 7-12).

Stoner, drawn to microbicidal cleansers for preventing sexually transmitted diseases and AIDS, discloses that spermicide compounds such as nonoxynol-9 used in foams also act as anti-microbial agents (see col. 1, lines 53-58).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the prior art discussed above to make a package containing a condom and an antiviral composition which comprises a microbicidal agent, a buffer and a wound healing and diffusion impedance compound, since the ingredients for the same are seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to do so since combining the composition of Larsen to include dextran sulfate or hyaluronic acid would give a composition that would have a wide spectrum of antimicrobial activity which prevents not only pregnancy and sexually transmitted diseases during sexual encounter but also maintains and enhances the protective function of the vaginal flora (Larsen, col. 3, lines 5-12).

Claims 11-12 drawn to the package wherein the composition has specific percentages of spermicidal agent, buffering agent and hyaluronic acid, polyacrylic acid are allowable.

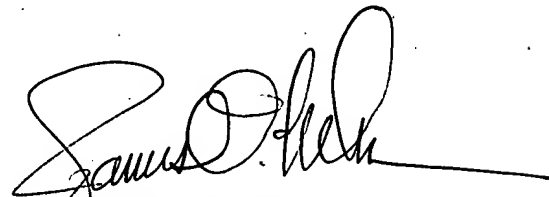
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK  
July 25, 2003



**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**